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**Summary of Safety and Effectiveness
Smith & Nephew Orthopaedics Inc.
Reflection Acetabular Reinforcement Rings**

Substantial Equivalence Information

The Reflection Acetabular Reinforcement Rings System is similar to the following systems:

1. Trilogy™ Acetabular System - Zimmer
2. Porous Ringloc Acetabular System - Biomet
3. S-ROM™ Oblong Component - Joint Medical Products Corporation
4. MARS® Ringloc Component - Biomet
5. Healey Flanged Component - Biomet
6. Original M.E. Müller Acetabular Roof Reinforcement Ring - Protek Ltd.
7. H.B. Burch- R. Schneider Reinforcement Cage
8. R. Ganz Acetabular Roof Reinforcement Ring with Hook - Intermedics
9. Gap Acetabular Cup - Osteonics
10. Oh-Harris Protrusio Shell - Howmedica

All of the devices listed above are similar in design to the Reflection Acetabular Reinforcement Rings System. The safety and effectiveness of the Reflection Acetabular Reinforcement Rings System is based on the long history of use of these devices in the market place.

Device Description

The Reflection Acetabular Reinforcement Ring is a device intended to address acetabular defects. The rings are manufactured from titanium in a variety of sizes to accommodate the needs of patients.

Indications for Use

The Reflection Acetabular Reinforcement Ring System is indicated as follows: rheumatoid arthritis, avascular necrosis, femoral neck fractures, osteomyelitis, fracture-dislocation of the hip, and unsuccessful cup arthroplasty, endoprosthesis, femoral osteotomy, or girdlestone resection. Indications also include osteoarthritis, traumatic arthritis, slipped capita epiphysis, fused hip, and diastrophic variant. Reflection Acetabular Reinforcement Rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and / or protrusion as a result of the indications listed previously. The device is for single use.